General

Guideline Title

Final recommendation statement: gynecological conditions: periodic screening with the pelvic examination.

Bibliographic Source(s)

Final recommendation statement: gynecological conditions: periodic screening with the pelvic examination. [internet]. Rockville (MD): U.S. Preventive Services Task Force (USPSTF); 2017 Mar [7 p]. [25 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of performing screening pelvic examinations in asymptomatic, nonpregnant adult women (I statement).

This statement does not apply to specific disorders for which the USPSTF already recommends screening (i.e., screening for cervical cancer with a Papanicolaou ["Pap"] smear, screening for gonorrhea and chlamydia). See the eTable in the guideline supplement.

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to asymptomatic women 18 years and older (see Figure 2 in the original guideline document) who are not at increased risk for any specific gynecologic conditions, such as ovarian or cervical cancer. The recommendation does not apply to pregnant women or adolescents.

Suggestions for Practice Regarding the I Statement

Potential Preventable Burden

Numerous gynecologic conditions may be detected during a screening pelvic examination. These include malignant diseases, such as ovarian, uterine, vaginal, and cervical cancer; infectious diseases, such as bacterial vaginosis, candidiasis, genital warts, genital herpes, trichomoniasis, and pelvic inflammatory disease; and other benign conditions, such as cervical polyps, endometriosis, ovarian cysts, dysfunction of the pelvic wall and floor, and uterine fibroids.

The accuracy of detecting and the benefit of treating some of these conditions early, while women are asymptomatic, is unknown. No studies evaluated the effectiveness of early diagnosis and treatment of screen-detected, asymptomatic gynecologic conditions compared with the diagnosis and treatment of symptomatic gynecologic conditions. It is also unknown whether performing screening pelvic examinations more frequently than every 3 to 5 years (the recommended screening interval for cervical cancer) is beneficial. Although it is common practice to perform a pelvic examination as part of an annual physical examination, the benefit of performing screening pelvic examinations at this interval is unclear. The benefit of using pelvic examination alone to screen for gynecologic conditions other than cervical cancer, gonorrhea, and chlamydia is also unknown.

Potential Harms

The USPSTF found limited evidence on the harms of screening with pelvic examination. Harms reported in studies included false-positive and false-negative results. Available evidence reports false-positive rates for ovarian cancer of 1.2% to 8.6% and false-negative rates of 0% to 100%. Pelvic examination screening also could result in unnecessary diagnostic workup and treatment. In particular, there is a concern for potential invasive diagnostic procedures and treatment of ovarian cancer (such as surgery) that could result from evaluating abnormal findings on pelvic examination. In the reviewed studies, approximately 5% to 36% of women who had abnormal pelvic examination findings went on to have surgery. The potential association between urinary tract infections and pelvic examinations was explored in a single study, with inconclusive results. Additional theoretical harms of pelvic examination include psychological harms (anxiety), pain and discomfort from the examination, and the potential for these harms to serve as a barrier for women to receive medical care.

In the absence of clear evidence on the balance of benefits and harms of using pelvic examination to screen for asymptomatic gynecologic conditions, clinicians are encouraged to consider the patient's risk factors for various gynecologic conditions and the patient's values and preferences, and engage in shared decision making with the patient to determine whether to perform a pelvic examination.

Current Practice

According to the National Ambulatory Medical Care Survey, an estimated 44.2 million pelvic examinations were performed in 2012. In a 2010-2011 nationally representative survey of obstetricians and gynecologists, almost all surveyed clinicians indicated that they would perform a bimanual examination on asymptomatic patients during routine visits. According to another survey performed in 2009, 78% of surveyed clinicians (including obstetricians/gynecologists, family or general practitioners, and internists) believed that pelvic examination is useful for screening for gynecologic cancer in asymptomatic women; approximately 50% to 60% reported believing that pelvic examination is useful for cervical cancer screening, 49% to 70% for ovarian cancer (70% of obstetrician/gynecologists vs. 49% to 50% of internists and family practitioners), 39% to 45% for uterine cancer, 57% to 62% for vaginal cancer, and 53% to 62% for vulvar cancer (estimates are based on graphic display of data; exact numbers were not provided). Nearly all surveyed clinicians (97%) believed that the pelvic examination included bimanual examination, while most (69%) believed that the pelvic examination included rectovaginal examination.

Other Considerations

Screening Tests

For the purposes of this recommendation, the term "pelvic examination" includes any of the following components, alone or in combination: assessment of the external genitalia, internal speculum examination, bimanual palpation, and rectovaginal examination.

Useful Resources

Screening for cervical cancer, gonorrhea, and chlamydia are not included in this recommendation statement on screening pelvic examinations because they are already addressed in separate USPSTF recommendations. Screening for ovarian cancer with preventive services other than pelvic examination is addressed in the USPSTF's recommendation on screening for ovarian cancer; the USPSTF also has recommendations on counseling to prevent sexually transmitted infections. The Women's Preventive Services Guidelines, supported by the Health Resources & Services Administration, is another resource.

Definitions

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Gynecologic conditions other than cervical cancer, gonorrhea, and chlamydia

Guideline Category

Prevention

Screening

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To issue a new U.S. Preventive Services Task Force (USPSTF) recommendation on screening with pelvic examination for gynecologic conditions other than cervical cancer, gonorrhea, and chlamydia, for which the USPSTF has already made specific recommendations

Target Population

Asymptomatic, nonpregnant women 18 years and older who are not at increased risk for any specific gynecologic conditions, such as ovarian or cervical cancer

Interventions and Practices Considered

Pelvic examination (assessment of the external genitalia, internal speculum examination, bimanual palpation, rectovaginal examination)

Major Outcomes Considered

- Key Question 1: What is the direct evidence for the effectiveness of the pelvic examination in (a) reducing all-cause mortality, (b) reducing cancer- and disease-specific morbidity and mortality, and (c) improving quality of life?
- Key Question 2: What are the test performance characteristics of the pelvic examination (sensitivity, specificity, and positive and negative predictive values) in screening for gynecologic cancers and other gynecologic conditions?
- Key Question 3: What are the adverse effects of screening by pelvic examination?

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Sources and Searches

MEDLINE, PubMed (publisher-supplied references only), and the Cochrane Central Register of Controlled Trials were searched to locate primary studies informing the key questions (see the eMethods in the systematic review supplement) and published from the earliest date indexed (1946 for MEDLINE) through January 13, 2016. The database searches were supplemented with experts' suggestions and reference lists from all other recent systematic reviews. ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform were searched for ongoing trials. The National Cancer Institute provided previously unpublished data on the subset of randomized women from the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial who had undergone bimanual palpation of the ovaries and adnexa as well as rectovaginal examination; the 5-year follow-up results were subsequently published. Since January 2016, ongoing surveillance was conducted through article alerts and targeted searches of high-impact journals to identify major studies published in the interim that may affect the conclusions or understanding of the evidence and therefore the related USPSTF recommendation. The last surveillance was conducted on August 3, 2016, and identified no new studies.

Study Selection

Two investigators independently reviewed 8678 titles and abstracts by using an online platform (abstrackr20) and 316 articles (see Figure 2 in the systematic review) with specified inclusion criteria (see eTable 1 in the systematic review supplement). Discrepancies were resolved through consensus and consultation with a third investigator. Articles that did not meet inclusion criteria or those rated as poor quality were excluded; criteria for establishing study quality are noted in eTable 2 in the systematic review supplement. To avoid missing studies using the pelvic examination as a secondary screening test (e.g., ovarian cancer screening studies using cancer antigen 125 [CA-125] measurement and ultrasound technology that also included a pelvic examination component), reviewers were more inclusive during the review of abstracts and titles. As a result, many studies were excluded at the full-text review.

Eligible studies included unselected adult females who were not symptomatic or pregnant and were conducted in developed countries, as defined by "very high" development according to the 2014 United Nations Human Development Index. Studies conducted solely in symptomatic populations were excluded.

Any study that examined the relationship between pelvic examination and all-cause mortality, cancer- or disease-specific morbidity or mortality, or quality of life was eligible for inclusion. In addition, studies examining the screening accuracy of the pelvic examination in a single encounter or as a periodic program of screening were eligible.

Number of Source Documents

See the literature search flow diagram (Figure 2) in the systematic review (see the "Availability of Companion Documents" field) for a summary of evidence search and selection.

Articles included for Key Questions:

- Key Question 1: 0 articles
- Key Question 2: 10 articles (8 studies)

- Key Question 3: 11 articles (9 studies)

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

At least two reviewers critically appraised all articles that met the inclusion criteria using the Newcastle Ottawa Scale for cohort and case-control studies and Quality Assessment of Diagnostic Accuracy Studies I and II for studies of diagnostic accuracy, adapted to align with the U.S. Preventive Services Task Force's (USPSTF's) design-specific quality criteria (eTable 2 in the systematic review supplement [see the "Availability of Companion Documents" field]). The investigators rated articles as good, fair, or poor quality. In general, a good-quality study met all criteria, indicating low risk of bias. A fair-quality study did not meet, or it was unclear if it met, at least one criterion and also had no known important limitations that could invalidate its results. A poor-quality study had a single fatal flaw or multiple important limitations.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Extraction and Quality Assessment

One reviewer extracted study-level data into standardized evidence tables, and a second checked for accuracy. At least 2 reviewers critically appraised included studies using the Newcastle Ottawa Scales for cohort and case-control studies and Quality Assessment of Diagnostic Accuracy Studies I and II for studies of diagnostic accuracy adapted to align with the USPSTF's design-specific quality criteria (eTable 2 in the systematic review supplement). Disagreements in quality rating were resolved by consensus or consultation with a third independent reviewer. Included studies were limited to those published in English that were rated as good or fair quality using USPSTF quality-rating standards.

Data Synthesis and Analysis

Results were qualitatively synthesized by key question (see Figure 1 in the systematic review). For all of the studies of diagnostic accuracy, sensitivity and specificity were calculated in Stata version 13.1 (StataCorp), using Jeffrey confidence intervals from 2 × 2 tables constructed from data reported in the primary studies. In many cases the data presented differ slightly from the data in the published article because of these calculations. For diagnostic accuracy studies, in addition to the standard test performance characteristics (sensitivity, specificity, positive predictive value [PPV], and negative predictive value [NPV]), the following outcomes were calculated: condition prevalence in the study population, percentage of patients screening positive, false-positive rate, and false-negative rate. Since there were a limited number of studies for each condition, no pooled analyses were conducted.

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread

implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

**A*, *B*, *C*, *D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875. [5 references].

I Statements

For I statements, the USPSTF has a new plan to commission its Evidence-based Practice Centers to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205. www.annals.org .

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: for example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is especially important for preventive services with only insufficient evidence because providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.

Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty	Offer or provide this service.

Grade	Definition	Suggestions for Practice
	that the net benefit is moderate to substantial.	
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Cost Analysis

The U.S. Preventive Services Task Force (USPSTF) does not consider the costs of providing a service in this assessment.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review

Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send the draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF website from June 28, 2016, to July 25, 2016. One concern expressed in the comments was the perception that the USPSTF was recommending against performing screening pelvic examinations and therefore against screening for cervical cancer. The USPSTF has clarified that it is recommending neither for nor against screening with pelvic examination for gynecologic conditions other than cervical cancer, gonorrhea, or chlamydia. The evidence on performing pelvic examinations to screen for conditions other than cervical cancer, gonorrhea, or chlamydia is currently lacking, and the USPSTF is unable to determine the overall balance of benefits and harms. However, as it has previously, the USPSTF continues to recommend screening for cervical cancer, gonorrhea, and chlamydia in separate recommendation statements. Some comments also expressed concern that the USPSTF based its recommendation on costs. The USPSTF has clarified that it does not consider the costs of a preventive service when determining a recommendation grade; it bases its recommendations on the quality and strength of the available evidence about the potential benefit and harms of a preventive service. Comments also expressed concern that the USPSTF did not sufficiently consider the harms of performing pelvic examinations and that the USPSTF should have recommended against performing them. The USPSTF reviewed all available relevant studies that reported on harms of pelvic examinations. Too few studies were available for the USPSTF to determine the net benefit or harm of performing screening pelvic examinations.

Comparison with Guidelines from Other Groups

Recommendations for screening from the following groups were discussed: the American College of Physicians, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the Well-Woman Task Force, convened by the American College of Obstetricians and Gynecologists.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Benefits of Screening

The U.S. Preventive Services Task Force (USPSTF) found inadequate evidence on the benefits of screening for a range of gynecologic conditions with pelvic examination. No studies were identified that evaluated the benefit of screening with pelvic examination on all-cause mortality, disease-specific morbidity or mortality, or quality of life.

Potential Harms

Harms of Screening

The U.S. Preventive Services Task Force (USPSTF) found inadequate evidence on the harms of screening for a range of gynecologic conditions with pelvic examination. A few studies reported on false-positive rates for ovarian cancer, ranging from 1.2% to 8.6%, and false-negative rates, ranging from 0% to 100%. Among women who had abnormal findings on pelvic examination, 5% to 36% went on to have surgery. Very few studies reported false-positive and false-negative rates for other gynecologic conditions. No studies quantified the amount of anxiety associated with screening pelvic examinations.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its Web site . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent

practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Final recommendation statement: gynecological conditions: periodic screening with the pelvic examination. [internet]. Rockville (MD): U.S. Preventive Services Task Force (USPSTF); 2017 Mar [7 p]. [25 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Mar

Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the U.S. Preventive

Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality (AHRQ) support the operations of the USPSTF.

Guideline Committee

U.S. Preventive Services Task Force

Composition of Group That Authored the Guideline

*Task Force Members**: Kirsten Bibbins-Domingo, PhD, MD, MAS (University of California, San Francisco); David C. Grossman, MD, MPH (Group Health Research Institute, Seattle, Washington); Susan J. Curry, PhD (University of Iowa, Iowa City); Michael J. Barry, MD (Harvard Medical School, Boston, Massachusetts); Karina W. Davidson, PhD, MASc (Columbia University, New York, New York); Chyke A. Doubeni, MD, MPH (University of Pennsylvania, Philadelphia); John W. Epling Jr, MD, MSEd (State University of New York Upstate Medical University, Syracuse); Francisco A.R. García, MD, MPH (Pima County Department of Health, Tucson, Arizona); Alex R. Kemper, MD, MPH, MS (Duke University, Durham, North Carolina); Alex H. Krist, MD, MPH (Fairfax Family Practice Residency, Fairfax, Virginia, Virginia Commonwealth University, Richmond); Ann E. Kurth, PhD, RN, MSN, MPH (Yale University, New Haven, Connecticut); C. Seth Landefeld, MD (University of Alabama at Birmingham); Carol M. Mangione, MD, MSPH (University of California, Los Angeles); William R. Phillips, MD, MPH (University of Washington, Seattle); Maureen G. Phipps, MD, MPH (Brown University, Providence, Rhode Island); Michael Silverstein, MD, MPH (Boston University, Boston, Massachusetts); Melissa Simon, MD, MPH (Northwestern University, Evanston, Illinois); Albert L. Siu, MD, MSPH (Mount Sinai Hospital, New York, New York, James J. Peters Veterans Affairs Medical Center, Bronx, New York); Chien-Wen Tseng, MD, MPH, MSEE (University of Hawaii, Manoa)

*Members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to https://www.uspreventiveservicestaskforce.org/Page/Name/our-members.

Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

Disclosures

All authors have completed and submitted the International Committee of Medical Journal Editors (ICMJE) Form for Disclosure of Potential Conflicts of Interest. Dr. Barry reported receiving grants and personal fees from Healthwise, a nonprofit, outside the submitted work. No other authors reported disclosures. Authors followed the policy regarding conflicts of interest described at https://www.uspreventiveservicestaskforce.org/Page/Name/conflict-of-interest-disclosures. All members of the USPSTF receive travel reimbursement and an honorarium for participating in USPSTF meetings.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Availability of Companion Documents

The following are available:

Evidence Reviews:

- Guirguis-Blake JM, Henderson JT, Perdue LA. Periodic screening pelvic examination: evidence report and systematic review for the U.S. Preventive Services Task Force. JAMA. 2017 Mar 7;317(9):954-66.
- Guirguis-Blake JM, Henderson JT, Perdue LA, Whitlock EP. Screening for gynecologic conditions with pelvic examination: a systematic review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 147. Publication No. 15-05220-EF-1. Rockville (MD): Agency for Healthcare Research and Quality; 2017 Mar. 75 p.

Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med. 2007;147:123-7.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med. 2007;147:117-22.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-5.
- Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205.

Available from the USPSTF Web site.

The following are also available:

- Gynecological conditions: periodic screening with the pelvic examination. Clinical summary. Rockville (MD): U.S. Preventive Services Task Force; 2017 Mar. 1 p. Available from the USPSTF Web site.

The Electronic Preventive Services Selector (ePSS) is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

Patient Resources

The following is available:

- Pelvic examinations in nonpregnant women. JAMA patient page. JAMA. 2017 Mar 7;317(9):984.

Myhealthfinder is a new tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on March 21, 2017. The information was verified by the guideline developer on April 12, 2017.

Copyright Statement

Requests regarding copyright should be sent to: Lisa S. Nicolella, Writer/Editor, Office of Communications, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857; E-mail: lisa.nicolella@ahrq.hhs.gov.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.